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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,073	07/30/2001	Richard O. Hilson	10004450-1	2655

7590 04/08/2004

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EXAMINER


SODERQUIST, ARLEN

ART UNIT PAPER NUMBER

1743

DATE MAILED: 04/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/919,073	HILSON ET AL.	
	Examiner	Art Unit	
	Arlen Soderquist	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-50,52 and 53 is/are pending in the application.
- 4a) Of the above claim(s) 48-50,52 and 53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1-5-04</u> . | 6) <input type="checkbox"/> Other: _____ |

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1. Newly submitted claims 48-50 and 52-53 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the originally submitted claims were directed to a generic method of exposing an array to a fluid and did not include a specific type of fluid (wash fluid), a specific time in the process (prior to scanning) a specific type of array (microarray) or steps to remove the fluid and dry the array prior to scanning. The method as claimed is distinct from the apparatus and methods based on the general nature of the claims as first presented being of a scope that it covered several possible methods but the instant claims are drawn to a very specific method that has not been search and would be have a different classification.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 48-50 and 52-53 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1 and 4-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holen in view of Panetz, Iwata and Stylli (last two newly cited and applied). In the patent Hollen teaches a reaction cartridge and carousel for a biological analyzer. A semi-automated biological sample analyzer and subsystems are provided to simultaneously perform a plurality of enzyme immuno assays for human IgE class antibodies specific to a panel of preselected allergens in

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each of a plurality of biological samples. A carousel is provided to position and hold a plurality of reaction cartridges. Each reaction cartridge includes a plurality of isolated test sites formed in a two dimensional array in a solid phase binding layer contained within a reaction well which is adapted to contain a biological sample to be assayed. The carousel and cartridges contain structures which cooperate to precisely position the cartridges in each of three separate dimensions so that each cartridge is positioned uniformly. An optical reader operating on a principle of diffuse reflectance is provided to read the results of the assays from each test site of each cartridge. Also provided is a subsystem which provides predetermined lot-specific assay calibration data which is useful for normalizing the results of various assays with respect to predetermined common standard values. The biological sample analyzer (10) includes a processing chamber (11) in which to test biological samples. A chamber door (12) is preferably hingedly mounted to the analyzer overlying the chamber to selectively close off and provide access thereto. Inset into the chamber door is a translucent viewing window (14) which allows an operator to view the activity within the processing chamber. The window preferably includes a reagent addition port (16) through which reagents can be introduced into the chamber without opening the chamber door. The processing chamber contains a holding rack, preferably in the form of a rotatable carousel (18) which holds and conveys reaction cartridges (80) in order to position the cartridges at stations to receive sample and selected reagents and for reading test results therefrom, and to provide agitation required for processing the samples. the carousel also functions as a very precise optical bench, accurately positioning each reaction cartridge relative to an optical reader (32) to facilitate accurate and repeatable reading of test results directly from the cartridges. The carousel is preferably disposed on a tilted axis. Rotation of the carousel about this tilted axis provides desirable agitation of the fluids in a reaction well (86) of each reaction cartridge thereby promoting faster and more complete reactions and allowing the use of smaller volumes of sample and reagents than has previously been possible. A wash/waste unit preferably is provided and includes chambers (22,24) for holding wash solution to be added to the reaction cartridges and waste fluid aspirated from the reaction cartridges. A wash manifold (26) functions both as a cover for the chambers and as a mount for wash tubing and waste tubing (21,23). Wash and waste fluids are caused to flow through wash and waste tubing by means of peristaltic pumps (25,27). Wash and waste fluids are preferably introduced into and removed

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from the reaction wells of reaction cartridges mounted on carousel by means of a fluid probe (28) which is mounted proximate the free end of a horizontal, pivotally-mounted probe arm (33). In a preferred embodiment, fluid access to a reaction cartridge is provided when the carousel conveys the reaction cartridge to a preselected wash of the biological analyzer. At this position, the tilt of the carousel causes any fluid in the reaction well to gravitate towards a corner of the reaction well for removal by aspiration with the fluid probe. The preferred reaction cartridge includes a test card (82) which includes an array of test sites (84) preferably in close proximity to each other. The test card is contained within a reaction well which is defined by a well wall (88). The reaction well is preferably provided with a removable, preferably transparent well cover (90) which preferably includes a reagent port (92) to facilitate the delivery and removal of fluids from the reaction well. The reaction cartridge also preferably includes code means (94) such as an optical bar code which is attached to or printed directly on the flat surface (91) of the reaction cartridge. The bar code is adapted to be read by the optical reader or by other conventional optical reader means and includes a lot code which is advantageously used to access stored assay calibration data corresponding to the particular reaction cartridge being tested. The test card is preferably a laminate structure comprising a binding layer (83) adhered to a non-absorbent substrate (85) using an adhesive such as a double-sided adhesive film (87). The capture reagent or assay binding component include any compound capable of directly or indirectly binding a desired component from a biological test sample. For example, a capture reagent or assay binding component may include antibodies, antigens, biotin, antibiotin, avidin, lectins, or peptide sequence probes, as well as combinations of the above (column 15 lines 9-19). The capture reagent can also be DNA for hybridization assays (column 13, lines 52-54). Columns 31-33 discuss the system control architecture of the analyzer including a bus (320). Columns 33-38 gives an explanation of the steps involved in the analysis including the manual steps of adding sample, conjugate, substrate and removing the cover. Holen is a semi-automated device and therefore requires operator intervention to place the reaction cartridge on the carousel and add fluids. As such Holen does not teach an input means or an output means or removing the cover prior to adding fluids.

In the patent Panetz teaches apparatus for automatically separating a compound from a plurality of discrete liquid specimens. In columns 1-2 Panetz discusses disadvantages with prior

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methods that include operator intervention to change a first batch of separating devices and introduce a second set of separating devices in a batch processing device. This problem is overcome by addition of structure to add new separation devices to the rotating carousel (figures 4-5 and their associated discussion) and remove used separating devices from the carousel after the separation is complete (figure 15 and its associated discussion). The device also has means to automatically add fluids to the separation devices. These mechanisms are taught as reducing the operator interface with the device, helping to prevent contamination and facilitating the continuous operation of the device (columns 2-4).

Iwata discloses an analyzing apparatus for applying samples and reagents to the surface of a reaction carrier and for optically analyzing each component contained in the various samples. The dispensing of the samples and reagents and the optical detection operation are performed by an optics/dispensing mechanism moved relative to the reaction carrier in two dimensions. The optics/dispensing mechanism is combined with a cleaning apparatus for cleansing reagents and samples from a dispensing needle by means of a rinsing agent and air ejected toward the needle. The apparatus further includes an automatic lifting mechanism for lifting and replacing a cover disposed on the reaction carrier, and is adapted to move the dispensing needle to a position over a nearby reagent/sample holder so that the needle may take up a desired reagent or sample from the holder and transfer it to the surface of the reaction carrier. The apparatus is capable of performing highly accurate analytical measurements fully automatically and in continuous fashion. An object of the invention is to provide an optical-type automatic analyzing and measuring apparatus which enables a variety of laboratory and clinical reactions to be analyzed and measured quantitatively and qualitatively absolutely without human intervention through automated dispensing and optical analysis of samples and reagents at predetermined positions in any desired sequence. Figures 13-17 show the covers and lifting mechanism. The lifting mechanism is adapted to lift a cover provided for the purpose of preventing the evaporation of water contained in the reaction carrier which is accommodated in a vessel, and to replace the cover following the dispensing of the prescribed reagent or sample or upon the completion of an optical measurement. The lifting mechanism can even lift and transport an object other than the cover and both raise and lower the object at a predetermined location. The lifting mechanism should be secured to the optics/dispensing mechanism at a

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position where the lifted object, such as the cover (71), will not impede the dispensing operation or the optical measurement, and so that the positional relationship among the lifting mechanism, optical system and dispensing mechanism will be fixed at all times.

In the patent Stylli teaches systems and methods that utilize automated and integratable workstations for identifying chemicals having useful activity. The invention is also directed automated workstations that are programmably controlled to minimize processing times at each workstation and that can be integrated to minimize the processing time of the liquid samples from the start to finish of the process. Figure 4 shows one embodiment of a sample distribution module with a conveyor means (210) comprising a rotating band that runs the length of the sample distribution module platform (220) and can transport plates. A bar code reader (230) registers plates on the conveyor means. A series of liquid handlers (240) are disposed along the conveyor means. Addressable wells in four chemical plates can be simultaneously aspirated from the liquid held in the liquid handlers, and then dispensed in additional plates. Lids can be removed or replaced by the delidder/lidder (250). Proximal and distal plate stackers (260) can be used temporarily to store plates, such as chemical and sample plates, which can facilitate plate selection. The sample distribution module can be operably linked to a sample transporter at an ingress/egress junction (270). Storage of work unit, such as plates, is accomplished with a rack system. A plurality of individual storage shelves is contained in a modular hotel (301). Modular hotels are mounted on an adjustable track system and attached to the store framework (302). The capacity of each hotel is typically about 20 to 40 shelves. The hotels are arrayed in the store in two dimensions, referred to as X and Z. Two opposing arrays of shelves are provided, with their entries on opposite sides of a central aisle (303). Traveling along the 'X' axis in the central aisle is a robotic means to store and retrieve work units. The robotic means can pick and place work units in any location in the storage and retrieval module. The robotic means comprises an integrated buffer to optimize the X axis travel. This can allow for the most efficient pick or place order via a programmed sequence of retrieval commands. The robotic means can operate on a plurality of plates without returning to the center input/output location except when the integrated buffer is fully loaded. The robotic end actuator also travels in the vertical or 'Y' direction. A platen device moves in the 'Y' axis to obtain units of work from the shelves, and can be used as a plate retrieval means as known in the art or developed in

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the future. At the ingress and egress location (304) in the center of the conveyor, there is a stacking or sorting means that can stack or sort work units. For instance, at the ingress, an upstacker creates a stack, which is transferred as a group to the robotic means. These units of work are then individually placed in the shelves of the storage and retrieval module. At the egress position, a down stacker (308) to separate units of work, and a sorting means (309) reorders the work units, so that units of work are presented to a sample transporter in the exact order required. The sample transporter (310) preferably connects to the storage and retrieval module near the center at the ingress and egress location to reduce travel time. The sample transporter can comprise a conveyor to transfer work units to workstations, and unload and offload means to assist the transfer of work units from devices, via photocells, a work unit inventory system (e.g., bar codes or other system). The sample transporter is capable of moving a unit at a rapid speed from any workstation to any other random workstation. It offers flexible parallel routing, unlike robotic means that only offer serial routing. This is a distinct advantage in drug discovery applications, and it can improve the reliability and flexibility of rapid liquid processing.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate input and output means into the Holen device and method such as taught by Stylli because of the reduced the operator interface with the device, reduced contamination and the ability for continuous operation of the device as taught by Panetz and Stylli. It would have been obvious to one of ordinary skill in the art at the time of the invention to use notoriously well known covers and provide means to remove the covers such as taught by Iwata or Stylli because of their well known use in preventing evaporation of fluids as taught by Iwata and if one were not concerned with the sealing advantages taught by Holen.

4. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. The changes to claim 48 took them beyond the examined scope and therefore form a different distinct invention that has not been search or examined.

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additional art shows various stacking means and includes the US Patent publication documents that were incorrectly cited in the IDS.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose current telephone number is (571) 272-1265 as a result of the examiner moving to the new USPTO location. The examiner's schedule is variable between the hours of about 5:30 AM to about 5:00 PM on Monday through Thursday and alternate Fridays.

A general phone number for the organization to which this application is assigned is (571) 272-1700. The fax phone number to file official papers for this application or proceeding is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


April 5, 2004

ARLEN SODERQUIST
PRIMARY EXAMINER